

REMARKS

Claims 1, 4-5, 6-11 and 13 are active.

Claim 1 is amended to incorporate Claims 2 and 3. Further support for amended claim 1 is found in the paragraph bridging pages 2-3 and Claims 6-7 as originally filed.

The specification is amended to include a reference to the earlier applications to which priority is claimed.

No new matter is added.

The claims of this application are to a scrubbing process of treating a skin irregularity that may include, wrinkles, fine lines, pigment marks, scars and others by applying high concentrations, e.g., at least 10% by weight of 8-hexadecene-1,16-dicarboxylic acid to the skin, leaving on the skin for 5 minutes to 30 minutes and then rinsing it off (see also page 2 of the application).

In the Official Action, the Examiner has raised a series of obviousness rejections. None of the cited documents, even in combination, teach or suggest to use of dioic acid in a scrubbing process in the amounts claimed nor is there motivation to do so in the 3 steps as recited in Claim 1.

The first set of rejections cites Harding (US 5,705,144), by itself, or combined with Reynolds (US 5,431,911) and/or Jones (US 2004/0126352). Harding teaches a composition including retinol with an dioic acid that is a general formula that includes 8-hexadecene-1,16-dicarboxylic acid as noted by the Examiner (see page 2 of the Official Action). Harding's purpose is to promote repair of photo-damaged skin and/or to lighten the skin. Reynolds is cited to support that removing a composition after it is applied is something that would have been obvious (see page 3 of the Official Action). Jones is cited to suggest that including salicylic acid in a chemical scrub would also have been obvious (see pages 3-4 of the Official Action).

Applicants respectfully disagree with the Examiner's conclusion of obviousness.

Harding relates to the reduction of melanine production. See col. 12, reproduced below:

The above procedure was used to assess the ability of compositions of dioic acids (at a range of concentrations) and retinol (at a range of concentrations) to reduce the amount of melanin produced without affecting cell viability.

These compositions were compared with compositions having retinol alone at a range of concentrations and dioic acids alone at a range of concentrations.

The results for both viability and melanin production were calculated as percentages of the control which contained medium alone. Results are given in Tables 3-7.

Results clearly show that dioic acids and retinol act synergistically to reduce melanin production. There were no effects on cell viability at these concentrations.

Therefore, Harding's teachings are that the dioic acids are to be applied to effectuate a biological mechanism and not a chemical one as is a chemical scrubbing process as claimed. Signs related to melanin production increase are those cited in the Abstract (e.g., melanine is induced when skin is exposed to sun UV). However it would not have been obvious starting from Harding to expect a decrease in skin irregularities by a chemical mechanism by way of a chemical scrub, which are well-known to the skilled person (see also the paragraph bridging pages 1-2 of the present application).

The Examiner simply concludes that either it is well-known to rinse off a composition or relies on Reynolds for this step in the claim (see page 3). However, a composition that is to be applied and effect a biological mechanism may need the composition to be kept on the skin and it would not be intended to be rinsed off. Even if the Examiner still maintains the unsupported allegation that Harding's composition is to be rinsed off, there are no teachings

in Harding, Reynolds and/or Jones to apply the composition for a specific range of time (from 5 minutes to 30 minutes) as recited in the claims before rinsing the composition off the skin. Indeed, Reynolds teachings have no basis to suggest leaving on a composition that specifically contains 8-hexadecene-1,16-dicarboxylic acid for the time specified in the claim and rinsing it off. Rather, Reynolds teachings are germane to a composition including almond meal, oatmeal, cosmetic clay, witch hazel and benzoin (see col. 2).

As to dependent claims 6 and 7 which teach a range of concentration for the 8-hexadecene-1,16-dicarboxylic acid exceeding the amounts taught by Harding, the Examiner alleges that the subject matter would have been obvious because the criticality of the amounts “is unclear to the examiner. . . and thus a manipulatable parameter.” See page 3 of the Action).

The Office has the initial burden of proof to establish the *prima facie* obviousness of the subject matter Applicants claim in view of the prior art teaching. *In re Oetiker*, 977F.2d 1443, 1445 (Fed. Cir. 1992). Absent evidence which supports a rejection of the subject matter Applicants claim for obviousness, the Examiner’s conclusion that Applicants’ claims are unpatentable under 35 U.S.C. §103(a) must be withdrawn. Simply stating that the application does not provide evidence, as has been done in the rejection, is insufficient as it attempts to shift the burden of proof to the Applicants without actually establishing even a semblance of a *prima facie* case.

Further and with respect to the allegation that the amount is a manipulatable parameter, there is simply no teachings in Harding that the concentration of 8-hexadecene-1,16-dicarboxylic acid in a chemical scrubbing process is a variable requiring optimization because Harding’s teachings do not, in fact, relate to a chemical scrubbing process. See also, .e.g., *In re Antonie*, 559 F.2d 618, 195 USPQ 6, 8-9 (CCPA 1977) (exceptions to rule that optimization of a result-effective variable is obvious, such as where the results of optimizing

the variable are unexpectedly good or where the variable was not recognized to be result effective). See also *Ex parte Whalen*, 89 USPQ2d 1078 (Bd. Pat. App. & Int. 2008).

Accordingly, the rejections citing Harding with or without Reynolds and/or Jones cannot be sustained.

The second set of rejections cites the research disclosure #477 cited on the International Search report with the internet article describing Aralalone also with Reynolds then further with Jones (see pages 4-5 of the Official Action). The research article suggests that the material can be used for anti-aging by promoting collagen production, skin lightening, age spot reduction and the treatment of acne. Reynolds is cited to argue that it would have been obvious to leave the composition on the skin and then rinse it off. Jones is cited for the same purpose as it was in the first set of rejections, i.e., to teach including salicylic acid.

Applicants respectfully disagree.

The research disclosure teaches a composition comprising from 0.0001 to 10% of dioic acid that is useful for day and night creams (as described in this document) and contrary to the Examiner's contention are intended to be kept on the skin and not to be rinsed off. In contrast, the scrubbing process presently claimed require high amounts of dioic acid (at least 10% or more). That is why rinsing off the composition is needed after application. This cited document encourage to use low amounts of dioic acid and accordingly the one skill in the art would not have been motivated to rinse off the composition as described in Reynolds.

The Examiner simply concludes that either it is well-known to rinse off a composition or relies on Reynolds for this step in the claim (see page 3-4 of the Action). However, a day/night cream is well-known by the skilled person to be applied and kept on the skin and it would not be intended to be rinsed off. Even if the Examiner still maintains the unsupported

allegation that the Research Disclosure #477 composition is to be rinsed off, there are no teachings in Research Disclosure #477, Reynolds and/or Jones to apply the composition for a specific range of time (from 5 minutes to 30 minutes) as recited in the claims before rinsing the composition off the skin. Indeed, Reynolds teachings have no basis to suggest leaving on a composition that specifically contains 8-hexadecene-1,16-dicarboxylic acid for the time specified in the claim and rinsing it off. Rather, Reynolds teachings are germane to a composition including almond meal, oatmeal, cosmetic clay, witch hazel and benzoin (see col. 2).

As to dependent claims 6 and 7 which teach a range of concentration for the 8-hexadecene-1,16-dicarboxylic acid exceeding the amounts taught by Research Disclosure #477, the Examiner alleges that the subject matter would have been obvious because the criticality of the amounts “is unclear to the examiner. . . and thus a manipulatable parameter.” See page 4 of the Action.

The Office has the initial burden of proof to establish the *prima facie* obviousness of the subject matter Applicants claim in view of the prior art teaching. *In re Oetiker*, 977F.2d 1443, 1445 (Fed. Cir. 1992). Absent evidence which supports a rejection of the subject matter Applicants claim for obviousness, the Examiner’s conclusion that Applicants’ claims are unpatentable under 35 U.S.C. §103(a) must be withdrawn. Simply stating that the application does not provide evidence, as has been done in the rejection, is insufficient as it attempts to shift the burden of proof to the Applicants without actually establishing even a semblance of a *prima facie* case.

Further and with respect to the allegation that the amount is a manipulatable parameter, there is simply no teachings in Research Disclosure #477 that the concentration of 8-hexadecene-1,16-dicarboxylic acid in a chemical scrubbing process is a variable requiring optimization because the Research Disclosure #477 teachings do not, in fact, relate

to a chemical scrubbing process. See also, .e.g., *In re Antonie*, 559 F.2d 618, 195 USPQ 6, 8-9 (CCPA 1977) (exceptions to rule that optimization of a result-effective variable is obvious, such as where the results of optimizing the variable are unexpectedly good or where the variable was not recognized to be result effective). See also *Ex parte Whalen*, 89 USPQ2d 1078 (Bd. Pat. App. & Int. 2008).

Accordingly, the rejections citing Research Disclosure #477 with or without Reynolds and/or Jones cannot be sustained.

The third set of rejections cites to DE 101 50 734 and its U.S. counterpart (US 2005/0008665) with Reynolds and then with Jones (see pages 6-7 of the Official Action).

The DE '734 publication is cited and acknowledged on page 1 of the present application (see lines 31-34) and teaches 8-hexadecene-1,16-dicarboxylic utility for pigment problems and suggests the use as a skin lightener (see also page 1 of the US counterpart) comprising 0.001 to 10% (preferably 0.005 to 5%) of dioic acid (see [0037], [0046], [0064], and claim 9). Reynolds and Jones are cited for the same purposes as in the first two sets of rejections.

Applicants respectfully disagree.

DE broadly teaches a composition comprising from 0.0001 to 10% of dioic acid but clearly when considering the entirety of the teachings of DE the amounts to be used are significantly less. However, when using high amounts of dioic acid, e.g., 10% or more as claimed (see also dependent Claims 6 and 7) rinsing off the composition is needed after application. Accordingly, in view of DE's teachings one skilled in the art would not have been motivated to rinse off the composition as concluded in the rejection with or without Reynolds. that is useful for day and night creams (as described in this document) and contrary to the Examiner's contention are intended to be kept on the skin and not to be rinsed off. In contrast, the scrubbing process presently claimed require high amounts of dioic acid (at least 10% or more). That is why rinsing off the composition is needed after application. This cited

document encourage to use low amounts of dioic acid and accordingly the one skill in the art would not have been motivated to rinse off the composition as described in Reynolds.

Even if the Examiner still maintains the unsupported allegation that the DE composition is to be rinsed off, there are no teachings in DE, Reynolds and/or Jones to apply the composition for a specific range of time (from 5 minutes to 30 minutes) as recited in the claims before rinsing the composition off the skin. Indeed, Reynolds teachings have no basis to suggest leaving on a composition that specifically contains 8-hexadecene-1,16-dicarboxylic acid for the time specified in the claim and rinsing it off. Rather, Reynolds teachings are germane to a composition including almond meal, oatmeal, cosmetic clay, witch hazel and benzoin (see col. 2).

As to dependent claims 6 and 7 which teach a range of concentration for the 8-hexadecene-1,16-dicarboxylic acid exceeding the amounts taught by DE, the Examiner alleges that the subject matter would have been obvious because the criticality of the amounts “is unclear to the examiner. . . and thus a manipulatable parameter.” See page 6 of the Action.

The Office has the initial burden of proof to establish the *prima facie* obviousness of the subject matter Applicants claim in view of the prior art teaching. *In re Oetiker*, 977F.2d 1443, 1445 (Fed. Cir. 1992). Absent evidence which supports a rejection of the subject matter Applicants claim for obviousness, the Examiner’s conclusion that Applicants’ claims are unpatentable under 35 U.S.C. §103(a) must be withdrawn. Simply stating that the application does not provide evidence, as has been done in the rejection, is insufficient as it attempts to shift the burden of proof to the Applicants without actually establishing even a semblance of a *prima facie* case.

Further and with respect to the allegation that the amount is a manipulatable parameter, there is simply no teachings in DE that the concentration of 8-hexadecene-1,16-

dicarboxylic acid in a chemical scrubbing process is a variable requiring optimization because the DE teachings do not, in fact, relate to a chemical scrubbing process. See also, .e.g., *In re Antonie*, 559 F.2d 618, 195 USPQ 6, 8-9 (CCPA 1977) (exceptions to rule that optimization of a result-effective variable is obvious, such as where the results of optimizing the variable are unexpectedly good or where the variable was not recognized to be result effective). See also *Ex parte Whalen*, 89 USPQ2d 1078 (Bd. Pat. App. & Int. 2008).

Accordingly, the rejections citing DE with or without Reynolds and/or Jones cannot be sustained.

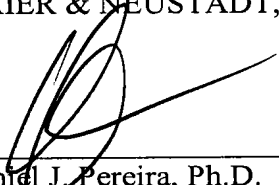
Allowance of the claims is requested.

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